Remarks

Claims 8 and 38 are amended. No claims are added or cancelled. Thus, claims 8, 10-12, 23, 27, 34 and 38-43 are currently pending. Support for the amendments is provided in the instant specification, for example, at page 4, line 23 to page 5, line 4; and page 7, lines 1-5.

The 35 U.S.C. § 112 Rejections

The Examiner rejected claims 8, 10-12, 23, 27, 34 and 38-43 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Additionally, the Examiner rejected claims 8, 10-12, 23, 27, 34 and 38-43 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. While not conceding to the Examiner's rejections, Applicant has elected to delete the expression "using a spectrophotometer" from step ii) of claims 8 and 38. Applicant respectfully submits that the amendments to claims 8 and 38 obviate the 35 U.S.C. § 112(1) and (2) rejections of claims 8, 10-12, 23, 27, 34 and 38-43. Therefore, withdrawal of the 35 U.S.C. § 112, first and second paragraph, rejections is appropriate and respectfully requested.

The 35 U.S.C. § 103 Rejection

The Examiner rejected claims 8, 10-12, 23, 27, 34 and 38-43 under 35 U.S.C. § 103(a) as allegedly being unpatentable over DeGrella, Corns or Waymack in view of Davis, Sagusa, Simon and Christenson, Leissing or Mullins. Applicant respectfully traverses this rejection.

DeGrella *et al.* disclose a method of determining the concentration of total iron in a sample by a chromogenic reaction entitled Scattered Energy Attenuation (page 1476), which comprises a step of determining a background scattered intensity of a sample containing iron, I_o, followed by a step of measuring the scattered intensity of a sample containing iron and an iron chromogenic reagent, I_f. Values of I_f/I_o together with a calibration curve are used to determine the concentration of the total iron.

Waymack *et al.* disclose a method of determining serum cholesterol levels, which involves i) initially measuring the absorbance of a mixture of a serum sample and water as a sample blank, and adding a reagent to the mixture to form a reaction mixture, or ii) initially measuring

the absorbance of a mixture comprising a serum sample, water and reagent before significant reaction has taken place as the sample blank, and iii) measuring the absorbance of the reaction mixture following an incubation period. The measured absorbance of the blank is used to correct the absorbance of the reaction mixture.

Corns discloses a method of determining the concentration of serum calcium. The method involves measuring the absorbance of a mixture of a serum sample with buffered zincon to obtain a blank reading and measuring the absorbance of the same mixture of serum sample and buffered zincon after zinc-EGTA has been added to obtain a test reading. Alternatively, the blank and test readings can be performed using two separate portions of the same serum sample (two tube assay). The blank measurement is used to remove the background absorbance due to colored complexes of zincon with endogenous zinc and copper from the absorbance of the test reading and produce a corrected serum calcium measurement. Unlike step ii) of the presently claimed methods, the initial measuring step of the Corns method is, therefore, performed in the presence of a reaction step that generates a chromophore within the sample.

Davis discloses a method of estimating a change in the concentration of an analyte in a whole-blood sample due to the hemolysis of red blood cells, comprising separating a plasma fraction from the whole blood sample using a dry separation material, estimating the quantity of extracellular hemoglobin in the plasma fraction, estimating a change in the analyte concentration in the sample due to the hemolysis of whole blood cells, and adjusting the apparent concentration of the analyte to account for the proportion of same which is due to the hemolysis of red blood cells (column 6, lines 3-16; column 8, lines 40-56).

Sagusa discloses a colorimetric method for measuring components in a sample in the presence of interfering chromogens. In the method disclosed in Sagusa, a color former is added to blood samples for colouring, and measurements for specific components are determined based on the light absorbance caused by the colouring. The measurements for specific components are corrected by the degree of chyle, degree of hemolysis and degree of icterus, which are determined at different wavelengths.

The instantly claimed methods differ from the Scattered Energy Attenuation method of Degrella *et al.*, the method of Waymack *et al.*, and the method of Corns in that the recited step of measuring an absorbance or reflectance in the absence of a reaction step that generates a

chromophore (step ii) and the step of determining (step iv) are performed using separate portions of the same sample contained within different elements (i.e. a tube or a pipette tip in step ii) and an analysis slide in step iv)) rather than the same element. The presently claimed methods further differ from that of Corns in that the initial step of measuring an absorbance or reflectance (step ii) is conducted in the absence of a reaction step that generates a chromophore (step ii).

More particularly, none of the cited references teaches or suggests, individually or in combination, the presently claimed method of claims 8, 10-12, 23, 27 or 34 of determining a corrected concentration of an analyte in a specimen comprising both a blood substitute interferent and a non-blood substitute interferent, which comprises measuring an absorbance or reflectance of radiation of a specimen in a tube or a pipette tip in the absence of any reaction step that generates a chromophore within the specimen and determining the concentrations of the blood substitute interferent and the non-blood substitute interferent (steps ii) and iii)), followed by a step of determining an initial concentration of the analyte in the specimen disposed within an analysis slide with a slide analyzer and a step of correcting the initial concentration of the analyte. More specifically, none of the cited references teaches or suggests, individually or in combination, a method that includes a step of removing the contribution of both a blood substitute interferent and a non-blood substitute interferent from an initially measured concentration (apparent concentration) of an analyte to produce a corrected concentration of the analyte, as recited in claims 8, 10-12, 23, 27 or 34.

With respect to claims 38-43, none of the cited references, specifically teaches or suggests, individually or in combination, the instantly claimed method of determining a corrected concentration of an analyte in a specimen comprising a blood substitute interferent, which comprises measuring an absorbance or reflectance of radiation of a specimen in a tube or a pipette tip in the absence of any reaction step that generates a chromophore within the specimen and determining the concentration of the blood substitute interferent (steps ii) and iii)), followed by a step of determining an initial concentration of the analyte in the specimen disposed within an analysis slide with a slide analyzer and a step of correcting the initial concentration of the analyte.

Thus, the cited documents fail to disclose all of the elements of the claimed invention. Therefore, for at least this reason, the claims are not rendered obvious over DeGrella, Corns or

Waymack in view of Davis, Sagusa, Simon and Christenson, Leissing or Mullins. Accordingly, it is respectfully requested that the rejection of claims 8, 10-12, 23, 27, 34 and 38-43 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

JAMES SAMSOONDAR ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6905

Date Sept. 11, 2006 By Monique M. Perdok Shonka
Monique M. Perdok Shonka
Reg. No. 42,989

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 11TH day of September 2006.

PATRICIA A. HULTMAN

Name

Signature